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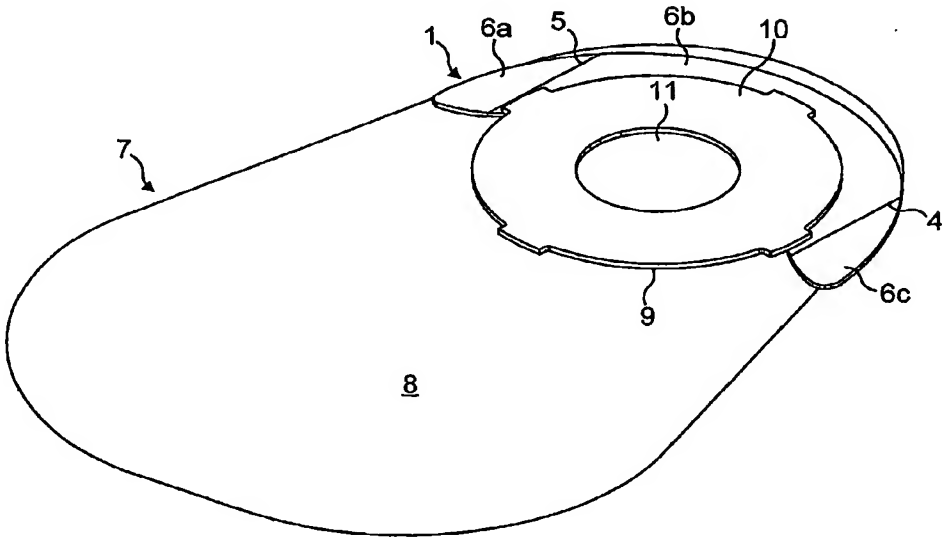
[Continued on next page]

(54) Title: A SUPPORT FOR AN OSTOMY BAG



(57) Abstract: The present invention provides a support (1) for an ostomy bag (7), the support extending the flange of the ostomy bag to reduce the risk of leakage. The support (1) is formed of a hydrocolloid layer (2) shaped to fit around a flange (9) of the ostomy bag. The support can be fitted to the flange at any appropriate location enabling the flange to be supported at the point at which it is prone to failing on a particular wearer.

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GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A SUPPORT FOR AN OSTOMY BAG

The present invention relates to a support for an ostomy bag, but is also applicable to wound drainage bags. For the purposes of the present specification, including the claims, all references to ostomy bags are to be interpreted to include wound-drainage bags and wound managers.

The main types of ostomy bags are colostomy bags, ileostomy bags and urostomy bags. These together with wound drainage or wound manager bags have in common that they form a seal around the stoma, or wound, through which waste material is drained from the body.

Ostomy bags comprise a receptacle for the waste having an aperture for receiving the waste. This aperture is normally surrounded by a flange of hydrocolloid adhesive. Hydrocolloid adhesive is particularly "skin friendly" comprising approximately 20% gelatine, 20% pectin and 20% carboxymethyl cellulose in an organic matrix of poly-isobutylene, which comprises the remaining 40% of the hydrocolloid adhesive.

The proportions of the components of the hydrocolloid adhesive may vary, but an important property of the material is that it is breathable. This is important because a particular problem with ostomy bags arises from the extended periods for which they have to be worn by a patient, normally 24 hours a day. This commonly results in maceration where the skin cannot breath and becomes saturated.

The wear time of an ostomy bag is often limited by the seal about the flange failing, whereby waste fluids from the body may leak past the seal, requiring the wearer to replace the ostomy bag, thus replacing the seal formed with the bag. This leakage is not only unpleasant and potentially embarrassing for the wearer, but the waste is also corrosive to the skin when the skin is exposed to the waste for any significant period of time. This together with any maceration that may occur reduces the likelihood of any subsequent ostomy bag correctly sealing.

Increasing the flange size on an ostomy bag might be thought to improve the sealing ability of the flange, however it is not desired to provide an excessively large flange because this in turn will expose a larger area of skin to the possible risk of maceration and also cause problems due to the flexing of the body under the area of the flange.

Ostomy bags thus normally have a standard size of flange that is considered appropriate for the "average" wearer. However, all wearers are different and some find that the standard flange of an ostomy bag does not seal, or fails before the ostomy bag is full. This often arises where there are bony protuberances close to the stoma or where stomal hernias arise, often as a side effect of the skin being cut to form the stoma.

There are currently two products available to a wearer who suffers problems with leaking ostomy bags. The first is hydrocolloid strip, formed by extruding and rolling hydrocolloid material. The strip is cut to length by a wearer and applied in the area where the flange seal normally fails. An alternative product used by some ostomy bag wearers is sold under the trade mark "SECUPLAST". This comprises an annular disk of tape covered with an acrylic adhesive. This is placed behind and around the flange of an ostomy bag

thereby extending the flange. However, a problem with this material is the acrylic adhesive is not as "skin friendly" as the hydrocolloid material and tends to increase skin trauma, which in turn causes problems with the subsequent fitting of further ostomy bags.

According to the present invention there is provided a support for an ostomy bag comprising a layer of hydrocolloid shaped to fit around and extend a portion of a flange of an ostomy bag.

Employing the present invention enables a wearer to fit a support in accordance with the present invention to that portion of the flange of an ostomy bag that is most prone to fail, when fitted to that particular wearer. The shaping of the layer of hydrocolloid, to fit around and extend the flange, ensures a large section of the circumference of the flange is extended whilst minimising the additional area of skin covered.

The invention is particularly advantageous in that it permits a standard support or range of supports to be used with one or more standard ostomy bags.

The hydrocolloid is self-adhesive on one side and covered by release paper arranged to be removed prior to use. This permits the hydrocolloid to be correctly positioned partially behind the flange and the release paper removed, such that the hydrocolloid support can be adhered to the flange in the correct position and, where the flange is provided with a similar release paper, the release paper of the flange then removed prior to mounting the ostomy bag upon the wearer.

Preferably, the hydrocolloid is semi-circular in shape, thus corresponding closely to the shape of the flange of the ostomy bag. Two hydrocolloid supports may be arranged in an opposed position about the flange, so that they extend around the complete circumference of the flange, thereby enabling the whole flange to be extended, where this is desired by a particular wearer.

The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which like numerals are used throughout to indicate like parts, and of which:

Figure 1A is a plan view of a support in accordance with the present invention;

Figure 1B is a side elevation of the support of Figure 1A;

Figure 2 is a perspective view of the support of Figures 1A and 1B;

Figure 3 is a perspective view of the support of Figure 2, showing the release paper partially peeled back;

Figure 4 illustrates an ostomy bag fitted with a support in accordance with present invention; and

Figure 5 illustrates an ostomy bag fitted with two supports in accordance with present invention.

Referring to Figures 1A, 1B and 2, a support for an ostomy bag in accordance with the present invention, indicated generally as 1, comprises a layer of 0.6 mm thick Hyperflex ™ hydrocolloid, an EU40 25μm thick polyurethane film backing 3 and a release paper divided by two cuts 4 and 5 into three sections 6a, 6b and 6c, the release paper being standard sterling coated paper. The properties of the hydrocolloid material 2 and

polyurethane film 3 are such that the support 1 is breathable when the release paper 6a, 6b, 6c is removed.

Figure 3 illustrates how the support 1 can be slightly flexed in the region of the slit 4 permitting the release paper to be held and peeled back. The release paper can similarly be removed starting at the slit 5.

Referring to Figure 4, there is illustrated a standard ostomy bag, illustrated generally as 7, comprising a receptacle portion 8, for receiving waste, and a flange 9. The flange 9 is formed of hydrocolloid material and has a release paper on its upper surface 10. In use the release paper is removed and the flange 9 centred on a stoma or wound of the wearer, such that fluid drains from the stoma or wound into the receptacle 8, via aperture 11 in the flange 9.

The support 1 of the present invention is placed in any desired position about the flange 9, and then slid partly behind the flange with the release paper 6a, 6b, 6c uppermost, as shown. In this position, starting at one of the slits 4 or 5, the release papers are peeled from the support 1 and the support adhered to the flange 9. Then the release paper (not shown) of the flange 9 is removed from the uppermost surface10 and the flange 9 and support 1 simultaneously adhered to the wearer.

As shown in Figure 5, a number of supports in accordance with the invention may be used on an ostomy bag, either to completely surround the flange as shown in Figure 5, to further extend the flange in a particular direction, that is to say further than it could be extended by use of a single support, or a number of supports may be built up in depth so as

to account for any depression in the surface of the wearer adjacent a stoma. Although not illustrated, it is possible that supports of different sizes may also be provided.

The present invention has been illustrated by way of example only and further embodiments may be apparent within the scope of the appended claims.

CLAIMS

1. A support for an ostomy bag comprising a layer of hydrocolloid shaped to fit around and extend a portion of a flange of an ostomy bag.

2. A support as claimed in Claim 1, wherein the layer of hydrocolloid is self-adhesive on one side.

3. A support as claimed in Claim 2, wherein the said self-adhesive side of the hydrocolloid layer is covered by a release paper arranged to be removed prior to use.

4. A support as claimed in any preceding claim wherein the hydrocolloid layer is semicircular.

5. A support as claimed in any preceding claim, arranged to cooperate with a similar support to form a collar extending around the complete circumference of the flange.

6. A support for an ostomy bag substantially as hereinbefore described with reference to, and/or as illustrated in, one or more of the accompanying figures.

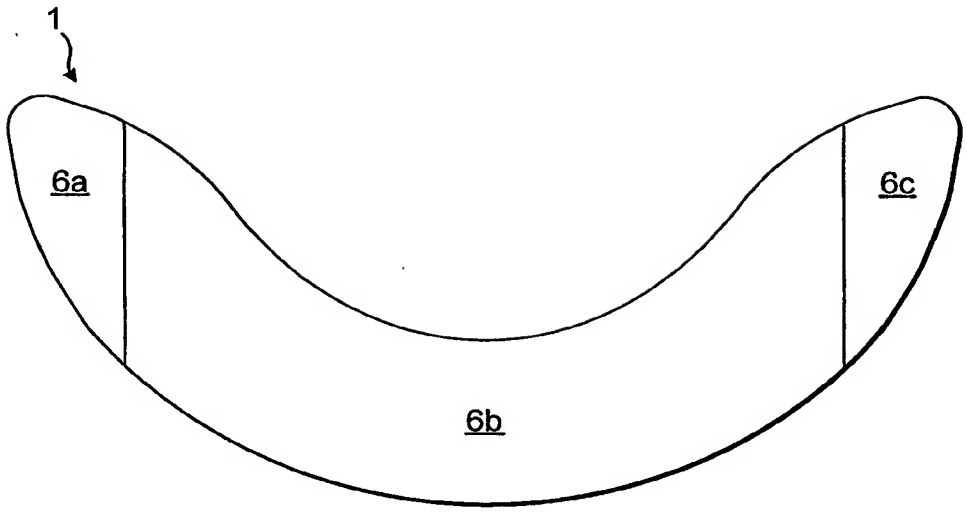

FIG. 1A

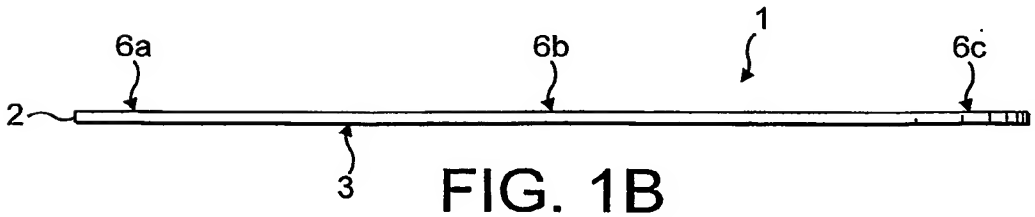

FIG. 1B

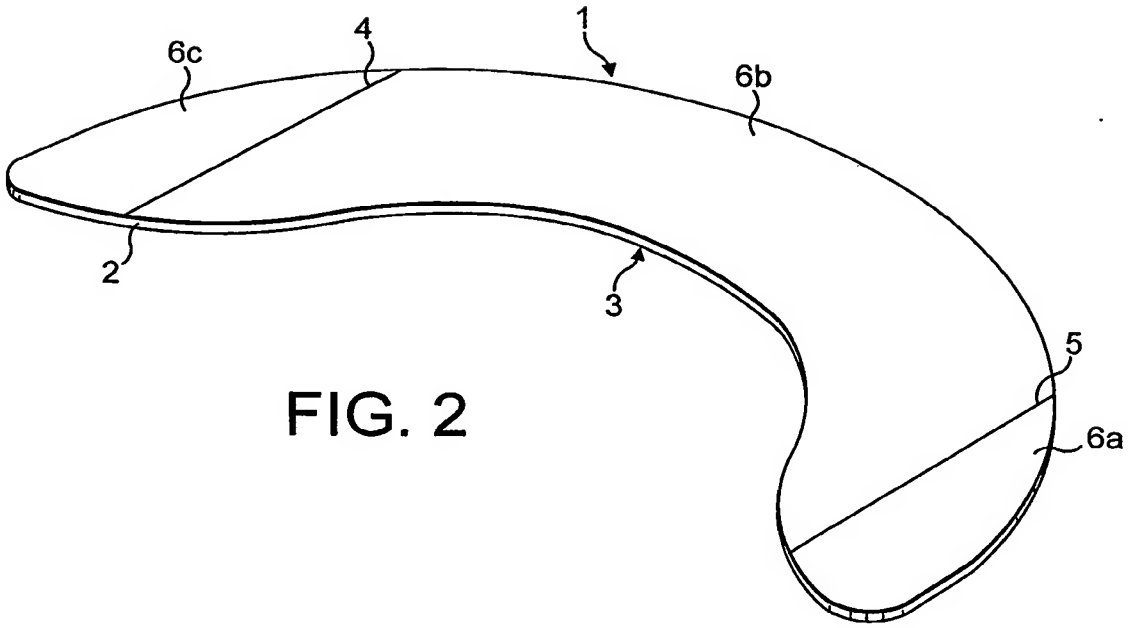

FIG. 2

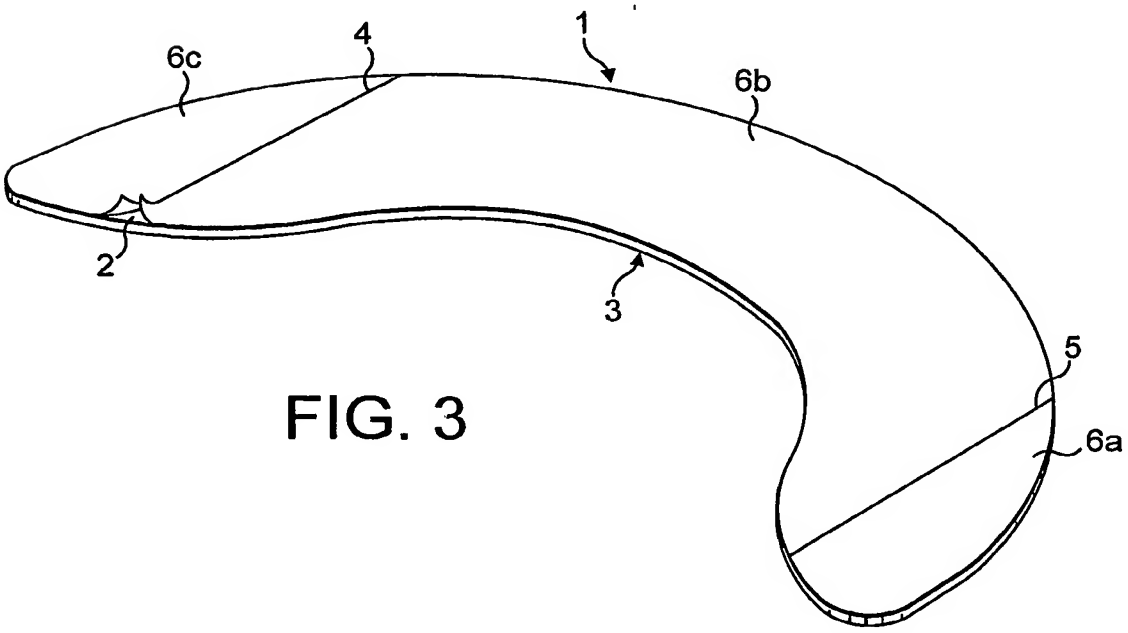

FIG. 3

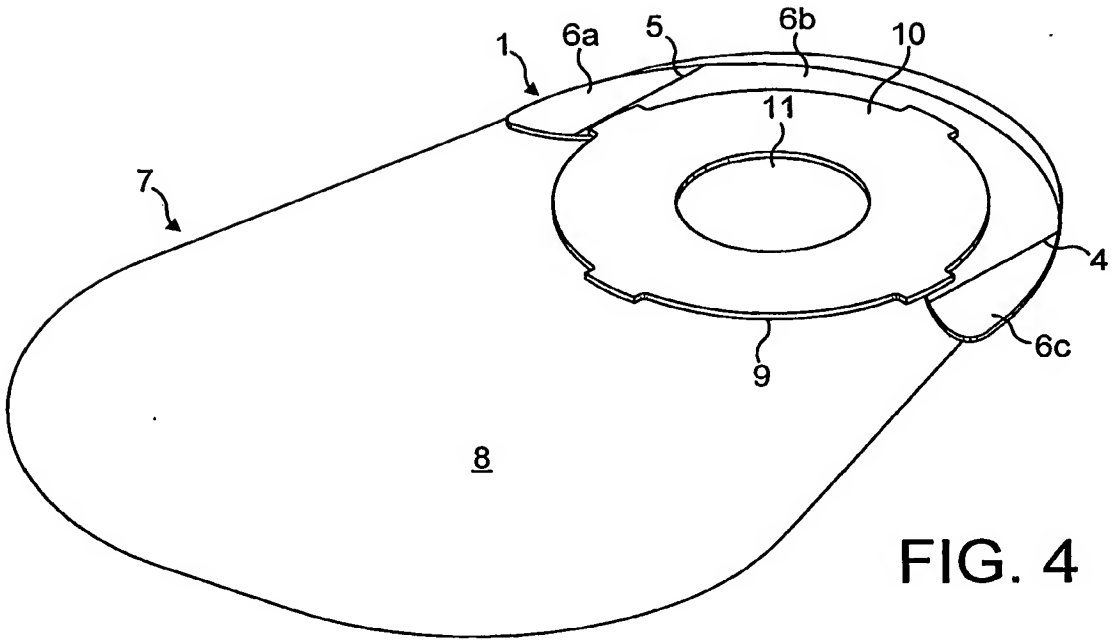

FIG. 4

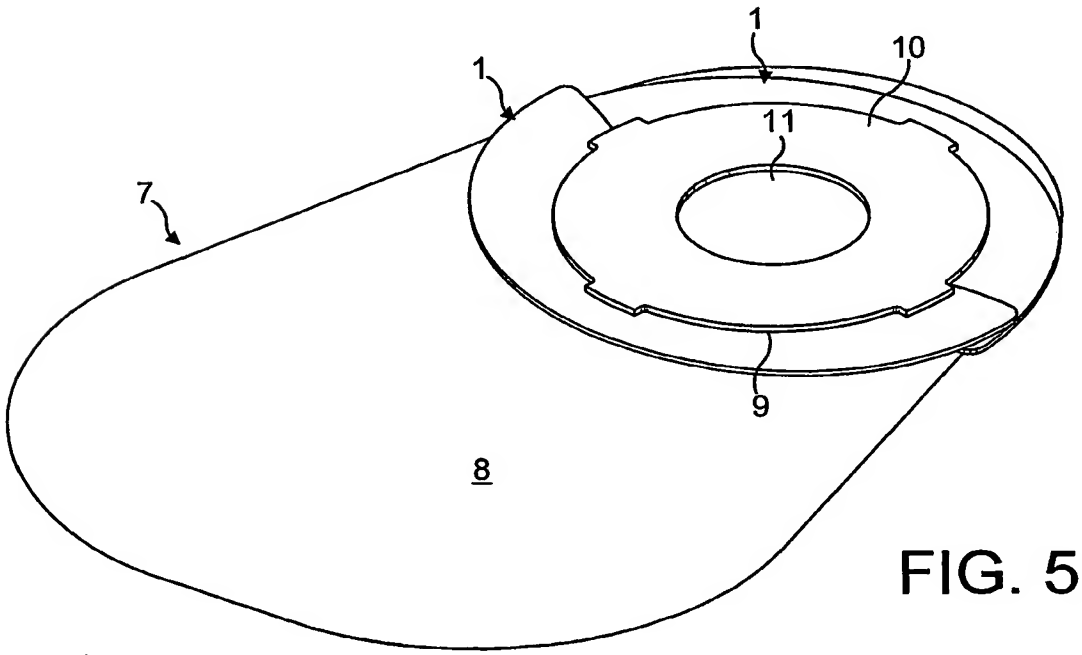

FIG. 5

INTERNATIONAL SEARCH REPORT

PCT/GB2004/000180

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F5/443 A61F5/448

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 039 464 A (ESPERANZA GALINDO) 19 June 1962 (1962-06-19) the whole document	1-5
X	US 2003/004477 A1 (GOTHJAELPSEN LAILA BUSK ET AL) 2 January 2003 (2003-01-02) paragraphs '0077!-'0081!; figure 9	1-5
A	WO 02/05735 A (HOOD WILLIAM) 24 January 2002 (2002-01-24) page 12, line 4 -page 13, line 15	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 May 2004	17/05/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Krassow, H

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2004/000180

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 6
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 6

Claim 6 seeks to define the invention by reference to the figures, and without defining any technical features (Article 6.2 PCT). The resulting lack of clarity is such that it is impossible to exactly determine the scope for which protection is sought rendering a meaningful search impossible.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

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